PATENT

PORTABLE GAS POWERED POSITIVE PRESSURE BREATHING APPARATUS AND METHOD

RELATED APPLICATION

This application is a continuation-in-part of provisional application no. 60/288,713, filed May 7,2001.

FIELD OF THE INVENTION

The present invention relates to an apparatus and method for use in respiratory therapy and more particularly to a portable system for use in supplying a continuous and/or dual level positive airway pressure treatment to a patient in respiratory distress and method. As used herein the term oxygen or O_2 includes air and oxygen enriched air as well as purified O_2.

BACKGROUND OF THE INVENTION

Individual's suffering from pulmonary edema, i.e., the effusion of serious fluid into the lungs, and certain other respiratory ailments are generally treated by forcing breathable gas, normally oxygen (O_2) into the lungs and maintaining the pressure within the lungs at a level, e.g., 1 to 20 centimeters of water above atmospheric. The O_2 can be supplied directly to the lungs through an endotracheal tube, one end of which is inserted into the lungs through the individual's mouth, i.e., intubation. The invasive technique of intubation

requires considerable skill and can cause serious injury to the patient. Also, the recovery time of intubated patients may be considerable.

Alternatively, a patient may be fitted with a breathing appliance such as a face mask which is equipped with an inlet for receiving oxygen under pressure and an inhalation/exhalation valve for exhausting exhaled air to the atmosphere. The respiratory departments of many hospitals have relatively sophisticated equipment for supplying oxygen at continuous and/ or dual level pressure to such appliances. However, such equipment is neither readily portable nor simple to operate and often is not available in emergency rooms.

Portable systems are currently available for use in emergency rooms by nurses and in the field by emergency rescue personnel, e.g., paramedics, for the continuous positive airway pressure ("CPAP") procedure. However, such portable systems conventionally rely on a spring loaded check valve located in or near the face mask to set the maximum pressure in the mask. The check valve serves to bypass the oxygen stream to the atmosphere during the patient's exhalation phase. The flow rate is normally adjusted to accommodate a patient's peak inhalation flow rate, e.g., 75 to 100 liters per minute (ℓ/m). A patient typically inhales around 10 to 12 ℓ/m with each exhalation phase exceeding the time duration of the inhalation phase by a factor of two or more.

As a result, currently available portable systems for use by emergency rescue personnel consume oxygen at a high rate stemming from the fact that they are continuous flow devices that must cater to high demand and waste O_2 during the longer expiration phase of the

respiratory cycle. Also, this high flow rate creates unwanted additional expiratory work for the patient.

In a normal respiratory cycle the torso muscles act to expand the lungs and thus draw air into them during the inhalation cycle. Exhalation is accomplished by the muscles relaxing and the elastic recoil of the chest forcing air from the lungs. During positive pressure breathing the muscle action is reversed so that air enters the lungs under pressure and exhalation requires forceful action by the abdominal muscles. Thus, exhalation under conventional CPAP treatment involves a significant amount of exertion for the patient.

The shock to a patient being suddenly confronted with a significant amount of pressure in his or her airway, e.g., 10 to 20 cm H_2O during inhalation/exhalation is another disadvantage of the currently available portable CPAP systems.

U.S. Patent No. 5,148,802 and related Patent Nos. 5,433,193 and 5,632,269, while not directed to portable CPAP systems for use by emergency rescue personnel, disclose a sophisticated system ("'802 system") employing the CPAP treatment for individuals suffering from sleep apnea. The '802 system, which is designed to keep the individual's airway continuously open during sleep, employs a sensitive flow sensor and complicated electronic circuitry to determine when the user is exhaling and lowers the applied pressure during the expiratory phase.

The '802 system is expensive and, as with many complicated electronic devices, would be subject to failure if mishandled.

There is a need for a simple, inexpensive, reliable, portable and rugged apparatus which can be used by emergency rescue personnel whether in the field or in emergency rooms to ventilate a patient's lungs with oxygen under continuous positive airway pressure.

SUMMARY OF THE INVENTION

A continuous positive airway pressure apparatus or system for supplying O_2 from a pressurized source to an individual's breathing appliance in accordance with the present invention includes a demand pressure regulator for supplying O_2 to the patient's breathing appliance, e.g., a face mask, only when demanded. The system includes a demand valve with a supply inlet port adapted to be connected to the pressurized source, an outlet port adapted to be connected to the appliance's inlet, a reference chamber and a valve assembly responsive to the reference chamber/appliance inlet pressure differential for connecting and disconnecting the inlet port to and from the outlet port.

The system further includes at least one manually adjustable back pressure regulator connected to the pressurized source and the reference chamber for setting the pressure in the reference chamber (and inlet to the breathing appliance) at a selected level above atmospheric pressure.

Optionally the system may include an additional manually adjustable or fixed back pressure regulator with one regulator controlling the back pressure during inhalation and the other controlling the back pressure during exhalation and connected to the reference chamber to act in parallel or series to create bi-level pressures. The system may also include a nebulizer

outlet for supplying low flow O_2 to a nebulizer during the patient's inhalation phase. In addition, a preferred patient valve to be attached to or incorporated in the breathing appliance may be used with the adjustable back pressure regulator/demand valve. The improved patient valve maintains the pressure in the patient's airway very close to the selected back pressure during inhalation and exhalation regardless of the magnitude of the selected pressure level. The improved patient valve is particularly advantageous where the reference back pressure remains the same during the entire breathing cycle.

A method of treating a patient suffering from pulmonary edema or other respiratory ailment in accordance with the present invention includes the following steps:

a) securing a breathing appliance to the patient's airway with the appliance having an inlet and an inhalation/exhalation valve to allow breathable gas passing through the inlet to enter the patient's lungs during the inhalation phase and allow expired air to exit to atmosphere during the exhalation phase;

b) providing a pressurized source of O_2;

c)providing at least one reference pressure at a selected value above atmospheric pressure;

d) monitoring the pressure at the appliance inlet;

e) comparing the appliance inlet pressure with the reference pressure;

f) connecting and disconnecting the pressurized source to the mask inlet when the inlet pressure falls below and rises to the reference pressure, respectively; and

g) varying the selected value of the reference pressure during the treatment.

The construction and operation of the present invention may best be understood by reference to the following description taken in conjunction with the appended drawings, wherein like components are designated with the same reference numeral in the several figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a system schematic of the present invention in an assembled state with a face mask and nebulizer;

Fig. 2 is a front view of a housing in which the various components of the invention are mounted;

Fig. 3 is a cross-sectional view of the components demand valve within the housing including a pressure regulator, pressure gauge, a maximum pressure relief valve and an anti-suffocation relief valve;

Fig. 4 is a cross-sectional view of the demand valve and the two relief valves;

Fig. 5 is a cross-sectional view of the pressure regulator;

Fig. 6 is a schematic cross-sectional view of a nebulizer which may be used with the invention;

Fig. 7 is a cross-sectional schematic view of the demand valve and pressure regulator showing the demand valve as configured during a patient's exhalation phase;

Fig. 8 is a cross-sectional schematic view of the demand valve and pressure regulator as configured during the inhalation phase;

Fig. 9 is a pressure diagram illustrating how the pressure at various points in the system changes with the flow rate;

Fig. 10 and 11 are cross-sectional schematic views of the nebulizer valve configured in the exhalation and inhalation modes, respectively;

Fig. 12 is a pressure diagram showing pressures at several points in the system relevant to the operation of the nebulizer valve;

Figs. 13 and 14 are schematic cross-sectional views of a bi-level controlled demand valve functioning with two independently adjustable pressure regulators in the exhalation and inhalation modes, respectively;

Figs. 15 and 16 are schematic cross-sectional views of a bi-level controlled demand valve with only one field adjustable pressure regulator configured in the exhalation and inhalation modes, respectively;

Figs. 17 and 18 are schematic cross-sectional views of an improved face mask valve for use with the invention as configured in the exhalation and inhalation modes, respectively; and

Fig. 19 is a top plan view of the face mask valve showing the angle through which the atmospheric outlet stub can swivel around the housing.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and particularly to the system schematic of the invention shown in Fig. 1, a demand oxygen regulator 10 is powered by a pressurized O_2 source 11 through an inlet port 12. An adjustable back pressure regulator 14 receives pressurized O_2 on conduit or line 15 through a flow restrictor 16. A pressure gauge 18 provides a measure of the pressure within the outlet 22 of a demand oxygen regulator 10. O_2, at the desired pressure, is supplied from the demand oxygen regulator outlet 22, to a mask 20, via an inlet

26a of a balanced inhalation/exhalation patient valve 26 attached to or incorporated into the mask, and a conventional hose or tube 25. The inlet 26a is hereinafter sometimes referred to as the breathing appliance inlet.

Low flow O_2 is also supplied to a nebulizer 26 from a nebulizer outlet 28 and a nebulizer shut off valve 30 (incorporated in the pressure regulator as will be described in more detail). The output of the nebulizer is combined with the O_2 delivered to the patient's mask through the tube 25 in a conventional manner.

Referring now to Figs. 2 and 3 the demand oxygen regulator 10, back pressure regulator 14 and pressure gauge 18 are mounted within a housing 32. The pressure gauge 18 is placed in fluid communication with the outlet 22 via line 31. Line 33 connects the outlet of a nebulizer valve (to be described) to the outlet 28. Line 34 connects a supply inlet 36 of the demand regulator 10 to the O_2 inlet nipple 12.

Referring now to Fig. 4 the demand O_2 regulator 10 includes a demand valve 40, a maximum pressure relief valve 38 and an anti-suffocation valve 39. The valves 38 and 39 are mounted in a housing 42 which is secured to the demand valve housing by bolts, for example. The upstream interior section of the housing 41 forms the outlet port 46 for the demand valve, as will be discussed in more detail in connection with Figs. 7 and 8.

The relief and anti-suffocation valves are conventional poppet valves with the valves 38 and 39 opening when the pressure in demand valve outlet 46 reaches a preset maximum value or falls below atmospheric pressure, respectively. The demand valve 40

includes the supply inlet 36, the outlet port 46, a reference pressure inlet 48 and a nebulizer valve outlet 50. The internal components of the demand valve 40 will be described in conjunction with Figs. 7 and 8.

Referring now to Fig. 5 the back pressure regulator valve 14 is a conventional poppet valve with a top housing section 14a, a lower housing section 14b, an inlet 14c connected to the pressurized source via restrictor 16 (Fig. 3), an atmospheric outlet port 14d, and a valve plate 14e which is biased against seat 14f by spring 14g. An axially moveable plunger 14h responds to the rotation of knob 14i to adjust the compressive force applied by the spring to the valve plate 14e which in turn restricts the flow in line 15 from the O_2 source 11 to adjust the back pressure at inlet 14c, e.g., 1 to 20 cm H_2O to establish the desired reference pressure in line 15a to the demand valve as will be described in connection with Figs. 7 and 8.

The nebulizer 26, as shown in Fig. 6, includes a container for liquid medication 26b. Pressurized O_2 leaving nozzle 26c educts vaporized medication into stream 26d which enters the tube 25 adjacent the face mask during the inhalation phase of the patient's breathing cycle.

Referring now to Figs. 7 and 8 the demand valve 40 includes a main or first diaphragm valve 52 in which first and second chambers 52a and 52b are disposed on opposite sides of a moveable diaphragm 52c. The diaphragm 52c closes against a seat 52d disconnecting pressurized passage 36a and the inlet 30 from passage 46a when the pressures in chambers 52a and 52b are equal due to the greater exposed surface area on the top versus the

bottom side of the diaphragm. A second diaphragm valve 54, which controls the operation of the main valve, has a pressure reference chamber 54a (open to the reference pressure inlet 48) and a second chamber 54b disposed on opposite sides of a sensing diaphragm 54c. The second valve also includes a normally closed spring biased paddle assembly comprising a pivotal arm 54d biased by spring 54e to normally close pilot valve orifice 54f.

The nebulizer (third) valve 30 includes chambers 30a and 30b, disposed on opposite sides of diaphragm 30c. The diaphragm 30c serves to close the nebulizer valve outlet 50 when the pressure in chambers 30a and 30b are equal due to the area of the diaphragm exposed to chamber 30b being greater than the area exposed to chamber 30a. A passageway 36b connects the chamber 30a to the inlet 36 as illustrated.

A passageway 36c connects the upper chamber 52a, the pilot valve orifice 54f and inner chamber 30a to the pressurized source via a flow restrictor 36d. Passageway 46e connects the lower chamber 54b of valve 54 to an outlet chamber 46c of the demand valve, which chamber extends above the outlet port and circumferentially around a nozzle 46b.

In the operation of the system of Figs. 7 and 8 the pressure regulator 14, having been preset to the desired positive mask pressure, provides that reference pressure e.g., 1 to 20 cm H_2O via line 15a to the reference chamber 54a. In the exhalation mode the main valve 52 is closed disconnecting the passage 46a and nozzle 46b from the inlet. When the patient begins to inhale the low pressure in the mask inlet, demand valve outlet port 46 and outlet chamber 46c falls slightly below the reference

pressure in chamber 54a, and as a result, the diaphragm 54c moves downwardly to engage the paddle valve assembly arm 54d, and lift it off of the pilot valve seat 54f. This bleeds the high pressure O_2 in line 36c to the lower pressure chamber 54b and the outlet port.

The flow restrictor 36d allows the pressure in chamber 52a to drop below the pressure in inlet passage 36a a sufficient amount to cause the main valve 52 to open as is illustrated in Fig. 8, to initiate the inhalation mode. The main valve will remain open as long as the pressure in the mask inlet and outlet chamber 46c remains below the reference pressure. When the patient initiates his or her exhalation phase the pressure in the outlet port 46 and chamber 54b will rise to the reference pressure thereby releasing the diaphragm 54c from the paddle wheel arm 54d and allowing the spring to close the pilot valve 54f. This action immediately allows the pressure in the line 36c and chambers 52a to rise to a level sufficient to close the main valve as is shown in Fig. 7.

In this manner O_2 is supplied to the patient only on demand and at a pressure level which can be determined by the operator prior to and/or during the treatment. This results in a considerable saving of O_2 over the O_2 consumed by the conventional portable CPAP systems.

There is a pressure drop across the hose or tubing which connects the mask inlet to the demand valve outlet port as well as in the mask valve itself, which pressure drop is proportional to the O_2 flow rate. The demand valve outlet chamber 46c and nozzle 46b compensate for this loss as is illustrated in Fig. 9. The pressure in outlet chamber 46c is decreased by flow through the

nozzle 46b, i.e., aspiration effect, in proportion to the flow rate. The nozzle and outlet chamber are designed, as illustrated in Fig. 9, to cause an increase in the pressure in the demand valve outlet port 46 (and decrease the pressure in the chamber 46c) which pressure increase mirrors the pressure drop across the tubing and mask valve as a function of flow rate. In this manner the resulting mask pressure is maintained almost equal to the adjusted reference pressure regardless of flow rate.

It is to be noted that the term pressure representative of the breathing appliance inlet pressure includes the pressure in the mask inlet and may include the demand valve outlet port pressure where the pressure loss in the tubing and/or patient valve is not compensated for.

The operation of the nebulizer valve 30 may best be understood by reference to Figs. 10-12. The inlet pressure, e.g., 50 psi, is applied to both chambers 30a and 30b of the third valve 30 in the static condition, i.e., pilot valve 54f and main valve 52 are closed. In the absence of O_2 flow through the main valve 52, e.g., exhalation mode, the diaphragm 30c closes the nebulizer outlet 50 due to the unequal areas of the diaphragm exposed to the opposing chambers. When the pilot and main valves open, at the initiation of inhalation, the pressure (P1) in passageway 36c decreases immediately, as explained earlier, allowing the diaphragm 30c to open the nebulizer valve. This allows O_2 to flow through restrictor 30d (Fig. 10), into the nebulizer outlet 50, through restrictor 54 to the nebulizer nozzle 26.

Fig. 12 is a pressure diagram showing the pressure at various points associated with the nebulizer during

inhalation and exhalation. Curves P1, P2 and P3 represent the pressure in line 36b, chambers 30b and outlet 50, respectively during the inhalation and exhalation modes as indicated.

A bi-level pressure regulator is illustrated in Figs. 13 and 14 configured in the exhalation and inhalation modes, respectively. An additional adjustable back pressure regulator 14′ and an inhalation/exhalation responsive or selector valve 56 enables an operator to adjust separate reference pressures for the exhalation and inhalation phases of the breathing cycle. The valve 56 includes chambers 56a and 56b disposed on opposite sides of a diaphragm 56c. The valve has outlet ports 56d and 56e connected to the inlets 14c and 14c′ of the pressure regulators 14 and 14′ as shown. A first inlet port 56f is connected to line 15 and the reference chamber 54a. A second inlet 56g is connected to nebulizer outlet, via line 58.

In the exhalation mode the pressure P3 (Fig. 12) in line 58 and chamber 56a is low and the valve 56 is open connecting the line 15 and reference chamber to the inlets of both pressure regulators. As a result the reference pressure is dictated by the pressure regulator having the lowest pressure setting, i.e., valve 14′. In the inhalation mode, with the main valve open, the pressure P3 in line 58 rises to force diaphragm 56c against the seat surrounding the outlet 56e thereby connecting only the inlet of the regulator 14 to the line 15 and the reference chamber. In this mode the reference pressure is set by the regulator 14.

Where the system is equipped with two independently adjustable pressure regulators, as in Figs. 13 and 14,

the exhalation pressure experienced by the patient may be adjusted to any level equal to or below (down to atmospheric pressure) the inhalation pressure. Thus, a patient's effort required to exhale may be considerably reduced.

An alternative embodiment of a bi-level system is illustrated in Figs. 15 and 16. This system functions in similar manner with one of the pressure regulators, i.e., regulator 55 being preadjusted at the factory to connect its input 55a to atmosphere via output 55b at a selected pressure, e.g., 10 cm H_2O. A selector diaphragm valve 57 connects the outlet 14d of pressure regulator 14 to atmosphere via line 59a, inlet port 57a, and outlet port 57b during the exhalation mode as is illustrated in Fig. 15. During the inhalation mode (Fig. 16) the rise in pressure in line 58 (P3, Fig. 12) transmitted through inlet orifice 57c causes diaphragm 57d to close outlet 57b, connecting the outlet of pressure regulator 14 to the inlet 55a of pressure regulator 55. Thus, the inhalation pressure will always be a fixed pressure (e.g., 10 cm H_2O) above the exhalation pressure as set by the manually adjustable pressure regulator 14.

It is to be noted that the term manually adjustable as used herein is not to be interpreted as limited to a rotatable knob arrangement. The term is to be interpreted to include any arrangement which allows the operator to readily change the reference pressure before and during a treatment.

Figs. 17 and 18 illustrate a cross-sectional schematic view of an improved patient valve arrangement 58 for use with or incorporation into a patient's face mask in accordance with this invention. The patient

valve 58 comprises an inlet passage 58a terminating in an inhalation check valve 58b that acts to permit flow from the inlet 58a to an inlet/outlet chamber 58c which in turn is adapted to be placed in fluid communication with the patient's airway via a face mask etc. A passage 58d conducts gas (O_2) from the inlet to a diaphragm chamber 58e. This chamber is formed by the upper surface of diaphragm 58f secured at its periphery to the inner wall of valve housing 58j, the upper top central surface 58g of a circular valve member 58h and the interior of an upper section 58i of the generally cylindrically shaped valve housing 58j as illustrated. The valve member 58h is secured to and suspended by the radially inner portion of the diaphragm. This chamber 58e acts to provide pneumatic damping and pressure balance to the operation of valve member 58h. When the patient exhales, the pressure in the inlet/outlet chamber 58c rises above the pressure in the inlet 58a. This causes check valve 58b to close, allowing diaphragm 58f and valve member 58h to move upwardly lifting the valve member off of its annular seat 58k formed at the upper (terminal) end of the inlet/outlet chamber 56c. Flow is then directed through an exhaust casing 58l which surrounds the valve seat and thence to exhaust port 58m and to atmosphere via passage 58n. The exhaust port, formed in exhaust casing 58l, which is rotatable through an angle of about 300° with respect to the valve housing 58j allows the patient's expired air to be directed as desired.

An important design feature of the valve is the balancing of the effective areas of the diaphragm 58f (and upper surface 58g of the valve member) and the valve seat area 58k. The effective area of the diaphragm has

a diameter d1 and the median diameter of the valve seat is d2. These two diameters are preferably about equal. This feature allows the exhalation pressure to be maintained at a level almost equal to the inhalation pressure in inlet 58a, regardless of the positive pressure level.

There has thus been described a novel apparatus or system for supplying breathable gas such as O_2 under the continuous positive airway pressure technique which is portable, rugged, simple to use and very conservative in its use of O_2. Various modifications and additions to the disclosed apparatus will occur to those skilled in the art without involving any departing from the spirit and scope of the invention as defined in the appended claims.